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YOUNG &amp; BASILE

NO. 558 P. 5



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/076,712	03/10/2005	Shinichiro Yokoyama	MOR-254-B	6564

48980 7590 08/25/2006

YOUNG & BASILE, P.C.  
3001 WEST BIG BEAVER ROAD  
SUITE 624  
TROY, MI 48084

EXAMINER

MENDEZ, MANUEL A

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 08/25/2006

AMD 11-25-06

Please find below and/or attached an Office communication concerning this application or proceeding.

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NOV 02 2006

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**Office Action Summary**

Application No.

11/076,712

Applicant(s)

YOKOYAMA ET AL.

Examiner

Manuel Mendez

Art Unit

3763

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 June 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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**DETAILED ACTION*****Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 recites the limitation "the distal and the proximal region thereof" in lines 5 and 6. There is insufficient antecedent basis for this limitation in the claim.

Additionally, the examiner objects to the preamble of this claim in view of the lack of terminology like comprising, including, or consisting, etc., linking the preamble with the body of the claim.

Claim 4 recites the limitation "the drugs or cells " in line 8. There is insufficient antecedent basis for this limitation in the claim. Please note that the term in question is only disclosed in the functional phrase "for administering a drug or cells" located in the preamble of claim 4. There is no positive disclosure of the phrase "for administering a drug or cells".

Claim 7 recites the limitation "the distal and proximal region of the target diseased area" in line 5. There is insufficient antecedent basis for this limitation in the claim.

In view of the above Section 112 problems, the examiner will maintain the rejections presented in the Office Action dated July 13, 2005. Since this application claims priority to a Japanese Patent, the examiner requests that applicant review each and every pending claim to ensure that the claim language in the pending claims conforms to U.S. Patent and Trademark Office practice.

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***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

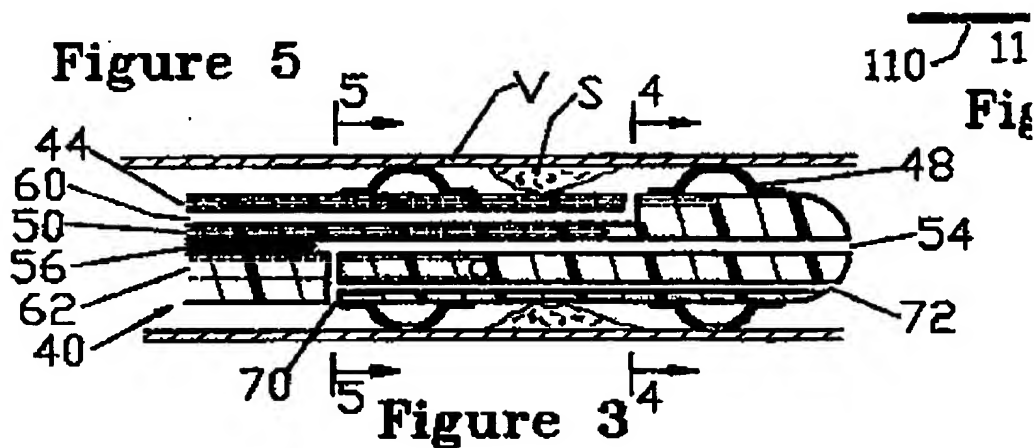
The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

**Claims 1 and 2** are rejected under 35 U.S.C. 102(b) as being anticipated by **Wright**.

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The Wright patent shows in figure 3, a balloon catheter having a plurality of lumens comprising an infusion lumen having a hole communicating with the outside of the catheter body between two balloons, balloon lumens to control expansion of the balloons, a bypass lumen, and a guidewire lumen. Based on the structural characteristics of the apparatus disclosed by Wright, all the functional limitations disclosed in claim 1 are considered inherent.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claim 3-8** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wright in view of Afzal, Bresnaham et al., and Macoviak et al. The Wright patent does not expressly disclose the use of the balloon catheter in diseased areas comprising cardiac muscle tissue. However, the use of balloon catheters having a bypass lumen in

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cardiac applications is conventional in the art as evidenced by the teachings of **Afzal, Bresnahan et al., and Macoviak et al.** These patents disclose balloon catheters having two balloons and a bypass lumen. Accordingly, for a person of ordinary skill in the art, modifying the catheter disclosed by Wright so that it can be used in areas of the heart would have been considered obvious in view of the conventionality of this particular intended use.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel Mendez whose telephone number is 703-272-4977. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Manuel Mendez  
Primary Examiner  
Art Unit 3763

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